



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Hartley *et al.*

Appl. No.: 10/815,730

Filed: April 2, 2004

For: **Recombinational Cloning
Using Nucleic Acids Having
Recombination Sites**

Confirmation No.: 1581

Art Unit: 1645

Examiner: Vogel, N.

Atty. Docket: 0942.285000N/BJD/JKM

First Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **AA20-AI20** are not provided in accordance with the Changes To Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan, effective October 21, 2004, which states "section 1.98(a)(2)(i) is amended to eliminate the requirement in paragraph (a)(2)(i) for a copy of each U.S. patent or U.S. patent application publication listed in an IDS in a patent application regardless of the filing date of the application." A copy of each other document is provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regard to non-English language documents **AL20** and **AM20** cited on Form PTO 1449:

Document **AL20**, French Patent Publication No. FR 2 670 502, is in the French language. Document **AM20**, PCT Patent Publication No. WO 92/10577, is in the French language. An unverified English language abstract of documents **AL20** and **AM20** is attached as document **AS213**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any

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foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

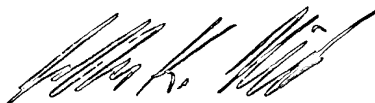
This First Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Jeffrey K. Mills
Agent for Applicants
Registration No. 56,413

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FORM PTO-1449

**FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT**

ATTY. DOCKET NO.
0942.285000N/BJD/JKM

APPLICATION NO.
10/815,730

INVENTORS(S)
Hartley *et al.*

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1645

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA20	5,451,513	09/19/1995	Maliga <i>et al.</i>			08/25/1993
	AB20	6,040,138	03/21/2000	Lockhart <i>et al.</i>			09/15/1995
	AC20	6,303,301	10/16/2001	Mack			05/29/1998
	AD20	6,309,822	10/30/2001	Fodor <i>et al.</i>			12/23/1996
	AE20	6,333,155	12/25/2001	Lockhart <i>et al.</i>			12/18/1998
	AF20	6,544,790	04/08/2003	Sabatini			09/18/2000
	AG20	2002/0162126	10/31/2002	Beach <i>et al.</i>			05/24/2001
	AH20	2003/0135888	07/17/2003	Zhu <i>et al.</i>			09/26/2002
	AI20	2003/0175772	09/18/2003	Wang			12/26/2002
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL20	FR 2 670 502	06/16/1992	France			Yes X No
	AM20	WO 92/10577	06/25/1992	WIPO			Yes X No
	AN20	WO 94/20604	09/15/1994	WIPO			Yes No
	AO20	WO 00/29000	05/25/2000	WIPO			Yes No
	AP20	WO 00/52027	09/08/2000	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>200</u>	Agah, R., <i>et al.</i> , "Gene Recombination in Postmitotic Cells. Targeted Expression of Cre Recombinase Provokes Cardiac-restricted, Site-specific Rearrangement in Adult Ventricular Muscle In Vivo," <i>J. Clin. Invest.</i> 100:169-179, The American Society for Clinical Investigation, Inc. (July 1997)
	AS	<u>200</u>	Benoist, C. and Chambon, P., "In vivo sequence requirements of the SV40 early promoter region," <i>Nature</i> 290:304-310, Macmillan Journals, Ltd. (1981)
	AT	<u>200</u>	Botstein, D., <i>et al.</i> , "Making Mutations <u>In Vitro</u> and Putting Them Back Into Yeast," in <i>From Gene to Protein: Translation into Biotechnology</i> , Ahmad, F., <i>et al.</i> , eds., Academic Press, New York, NY, pp. 265-274 (1982)

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	AL21	WO 00/52141	09/08/2000	WIPO			Yes No
	AM21	WO 01/25466	04/12/2001	WIPO			Yes No
	AN21	WO 01/42509	06/14/2001	WIPO			Yes No
	AO21	WO 02/46372	06/13/2002	WIPO			Yes No
	AP21	WO 02/62957	08/15/2002	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>201</u>	Broach, J.R., "The Yeast Plasmid 2 μ Circle," <i>Cell</i> 28:203-204, MIT (1982)
	AS	<u>201</u>	Cenatiempo, Y., "Prokaryotic gene expression <i>in vitro</i> : transcription-translation coupled systems," <i>Biochimie</i> 68:505-515, Elsevier (1986)
	AT	<u>201</u>	Christiansen, B., <i>et al.</i> , "A Resolvase-Like Protein Is Required for the Site-Specific Integration of the Temperate Lactococcal Bacteriophage TP901-1," <i>J. Bacteriol.</i> 178:5164-5173, American Society for Microbiology (September 1996)

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	AL22	WO 02/86144	10/31/2002	WIPO			Yes No
	AM22	WO 02/095055	11/28/2002	WIPO			Yes No
	AN22	WO 03/044207	05/30/2003	WIPO			Yes No
	AO22	WO 04/009768	01/29/2004	WIPO			Yes No
	AP22	WO 04/013290	02/12/2004	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>202</u>	Crellin, P.K. and Rood, J.I., "The Resolvase/Invertase Domain of the Site-Specific Recombinase TnpX Is Functional and Recognizes a Target Sequence That Resembles the Junction of the Circular Form of the <i>Clostridium perfringens</i> Transposon Tn4451," <i>J. Bacteriol.</i> 179:5148-5156, American Society for Microbiology (August 1997)
	AS	<u>202</u>	Ferrin, L.J. and Camerini-Otero, R.D., "Sequence-specific ligation of DNA using RecA protein," <i>Proc. Natl. Acad. Sci. USA</i> 95:2152-2157, National Academy of Sciences (March 1998)
	AT	<u>202</u>	Golic, K.G. and Golic, M.M., "Engineering the Drosophila Genome: Chromosome Rearrangements by Design," <i>Genetics</i> 144:1693-1711, The Genetics Society of America (1996)

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	AL23	WO 01/68836	09/20/2001	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

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	AR	<u>203</u>	Gottesman, S., "Bacterial Regulation: Global Regulatory Networks," <i>Ann. Rev. Genet.</i> 18:415-441, Annual Reviews, Inc. (1984)
	AS	<u>203</u>	Guo, F., <i>et al.</i> , "Structure of Cre recombinase complexed with DNA in a site-specific recombination synapse," <i>Nature</i> 389:40-46, Nature Publishing Group (September 1997)
	AT	<u>203</u>	Hallet, B. and Sherratt, D.J., "Transposition and site-specific recombination: adapting DNA cut-and-paste mechanisms to a variety of genetic rearrangements," <i>FEMS Microbiol. Rev.</i> 21:157-178, Elsevier Science B.V. (September 1997)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>204</u>	Hamer, D.H. and Walling, M., "Regulation <i>In Vivo</i> of a Cloned Mammalian Gene: Cadmium Induces the Transcription of a Mouse Metallothionein Gene in SV40 Vectors," <i>J. Mol. Appl. Genet.</i> 1:273-288, Raven Press (1982)
	AS	<u>204</u>	Hanks, S.K. and Hunter, T., "The eukaryotic protein kinase superfamily: kinase (catalytic) domain structure and classification," <i>FASEB J.</i> 9:576-596, The Federation of American Societies for Experimental Biology (May 1995)
	AT	<u>204</u>	Huang, L-C., <i>et al.</i> , "Convenient and Reversible Site-Specific Targeting of Exogenous DNA into a Bacterial Chromosome by Use of the FLP Recombinase: the FLIRT System," <i>J. Bacteriol.</i> 179:6076-6083, American Society for Microbiology (October 1997)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>205</u>	John, Jr., J.F. and Twitty, J.A., "Plasmids as Epidemiologic Markers in Nosocomial Gram-Negative Bacilli: Experience at a University and Review of the Literature," <i>Rev. Infect. Dis.</i> 8:693-704, University of Chicago (1986)
	AS	<u>205</u>	Johnston, S.A. and Hopper, J.E., "Isolation of the yeast regulatory gene <i>GAL4</i> and analysis of its dosage effects on the galactose/melibiose regulon," <i>Proc. Natl. Acad. Sci. USA</i> 79:6971-6975, National Academy of Sciences (1982)
	AT	<u>205</u>	Kendall, K.J. and Cohen, S.N., "Plasmid Transfer in <i>Streptomyces lividans</i> : Identification of a <i>kil-kor</i> System Associated with the Transfer Region of pIJ101," <i>J. Bacteriol.</i> 169:4177-4183, American Society for Microbiology (1987)

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	AR	<u>206</u>	Lyznik, L.A., <i>et al.</i> , "Activity of yeast FLP recombinase in maize and rice protoplasts," <i>Nucleic Acids Res.</i> 21:969-975, Oxford University Press (1993)
	AS	<u>206</u>	Maniatis, T., "Recombinant DNA Procedures in the Study of Eukaryotic Genes," in <i>Cell Biology: A Comprehensive Treatise, Volume 3, Gene Expression: The Production of RNA's</i> , Goldstein, L., and Prescott, D.M., eds., Academic Press, Inc., New York, NY, pp. 563-608 (1980)
	AT	<u>206</u>	Mayer, B.J. and Baltimore, D., "Signalling through SH2 and SH3 domains," <i>Trends Cell Biol.</i> 3:8-13, Elsevier Science (1993)

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	AR	<u>207</u>	McKnight, S.L., "Functional Relationships between Transcriptional Control Signals of the Thymidine Kinase Gene of Herpes Simplex Virus," <i>Cell</i> 31:355-365, MIT (1982)
	AS	<u>207</u>	Nunes-Düby, S.E., <i>et al.</i> , "λ Integrase cleaves DNA <i>in cis</i> ," <i>EMBO J.</i> 13:4421-4430, Oxford University Press (1994)
	AT	<u>207</u>	Odell, J., <i>et al.</i> , "Site-directed recombination in the genome of transgenic tobacco," <i>Mol. Gen. Genet.</i> 223:369-378, Springer-Verlag (1990)

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	AR	<u>208</u>	Peterson, B.Ø. and Shuman, S., "Hisitidine 265 Is Important for Covalent Catalysis by Vaccinia Topoisomerase and Is Conserved in All Eukaryotic Type I Enzymes," <i>J. Biol. Chem.</i> 272:3891-3896, The American Society for Biochemistry and Molecular Biology, Inc. (February 1997)
	AS	<u>208</u>	Rausch, H. and Lehmann, M., "Structural analysis of the actinophage ΦC31 attachment site," <i>Nucleic Acids Res.</i> 19:5187-5189, IRL Press (1991)
	AT	<u>208</u>	Sadowski, I., <i>et al.</i> , "A Noncatalytic Domain Conserved among Cytoplasmic Protein-Tyrosine Kinases Modifies the Kinase Function and Transforming Activity of Fujinami Sarcoma Virus P130 ^{gag-fps} ," <i>Mol. Cell. Biol.</i> 6:4396-4408, American Society for Microbiology (1986)

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	AR	<u>209</u>	Sauer, B. and Henderson, N., "Targeted Insertion of Exogenous DNA into the Eukaryotic Genome by the Cre Recombinase," <i>New Biol.</i> 2:441-449, Saunders Scientific Publications/W.B. Saunders Company (1990)
	AS	<u>209</u>	Senecoff, J.F., <i>et al.</i> , "The FLP recombinase of the yeast 2- μ m plasmid: Characterization of its recombination site," <i>Proc. Natl. Acad. Sci. USA</i> 82:7270-7274, National Academy of Sciences (1985)
	AT	<u>209</u>	Shaikh, A.C. and Sadowski, P.D., "The Cre Recombinase Cleaves the <i>lox</i> Site in <i>trans</i> ," <i>J. Biol. Chem.</i> 272:5695-5702, The American Society for Biochemistry and Molecular Biology, Inc. (February 1997)

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	AR	<u>210</u>	Shirai, M., <i>et al.</i> , "Site-Specific Integration of the Actinophage R4 Genome into the Chromosome of <i>Streptomyces parvulus</i> upon Lysogenization," <i>J. Bacteriol.</i> 173:4237-4239, American Society for Microbiology (1991)
	AS	<u>210</u>	Shuman, S., <i>et al.</i> , "Characterization of Vaccinia Virus DNA Topoisomerase I Expressed in <i>Escherichia coli</i> ," <i>J. Biol. Chem.</i> 263:16401-16407, The American Society for Biochemistry and Molecular Biology, Inc. (1988)
	AT	<u>210</u>	Shuman, S., "Site-specific Interaction of Vaccinia Virus Topoisomerase I with Duplex DNA. Minimal DNA Substrate for Strand Cleavage <i>In Vitro</i> ," <i>J. Biol. Chem.</i> 266:11372-11379, The American Society for Biochemistry and Molecular Biology, Inc. (1991)

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FORM PTO-1449

**FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT**

ATTY. DOCKET NO.
0942.285000N/BJD/JKM

APPLICATION NO.
10/815,730

INVENTORS(S)
Hartley *et al.*

FILING DATE
April 2, 2004

ART UNIT
1645

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>211</u>	Shuman, S., "Erratum: Site-specific Interaction of Vaccinia Virus Topoisomerase I with Duplex DNA. Minimal DNA Substrate for Strand Cleavage <i>In Vitro</i> ," <i>J. Biol. Chem.</i> 266:20576-20577, The American Society for Biochemistry and Molecular Biology, Inc. (1991)
	AS	<u>211</u>	Silver, P.A., <i>et al.</i> , "Amino terminus of the yeast <i>GAL4</i> gene product is sufficient for nuclear localization," <i>Proc. Natl. Acad. Sci. USA</i> 81:5951-5955, National Academy of Sciences (1984)
	AT	<u>211</u>	Stark, W.M., <i>et al.</i> , "Catalysis by site-specific recombinases," <i>Trends Genet.</i> 8:432-439, Elsevier Science (1992)

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	AR	<u>212</u>	Ulmanen, I., <i>et al.</i> , "Transcription and Translation of Foreign Genes in <i>Bacillus subtilis</i> by the Aid of a Secretion Vector," <i>J. Bacteriol.</i> 162:176-182, American Society for Microbiology (1985)
	AS	<u>212</u>	van Deursen, J., <i>et al.</i> , "Cre-mediated site-specific translocation between nonhomologous mouse chromosomes," <i>Proc. Natl. Acad. Sci. USA</i> 92:7376-7380, National Academy of Sciences (1995)
	AT	<u>212</u>	Ward, J.M., <i>et al.</i> , "Construction and characterisation of a series of multi-copy promoter-probe plasmid vectors for <i>Streptomyces</i> using the aminoglycoside phosphotransferase gene from Tn5 as indicator," <i>Mol. Gen. Genet.</i> 203:468-478, Springer-Verlag (1986)

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	AR	<u>213</u>	Invitrogen Life Technologies online catalog, "Directional TOPO Entry Vectors," 4 pages, accessed September 27, 2002, available at: http://www.invitrogen.com/content.cfm?pageid=3799&cfid=2897960&cftoken=88086554
	AS	<u>213</u>	Dialog File 351, Derwent World Patent Index, Unverified English Language Abstract for French Patent No. FR 2 670 502 (Document AL20) and PCT Patent No. WO 92/10577 (Document AM20), WPI Accession No. 9107201
	AT	<u>213</u>	Baum, J.A., "Tn5401, a New Class II Transposable Element From <i>Bacillus thuringiensis</i> ," <i>J. Bacteriol.</i> 176:2835-2845, American Society for Microbiology (1994)

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	AR	<u>214</u>	Short, J.M., <i>et al.</i> , "λ ZAP: a bacteriophage λ expression vector with <i>in vivo</i> excision properties," <i>Nucleic Acids Res.</i> 16:7583-7600, Oxford University Press (1988)
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